Section 5

K102027

DEC 2 2 2010

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date 06-04-10 [21 CFR 807.92(a)(1)].

A. Applicant Name and Address [21 CFR 807.92(a)(1)]

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B. Contact Information

Quantel USA

601 Haggerty Lane

Bozeman, MT 59715

Tel: 406-586-0131

Fax: 406-586-2924

Contact person: Michael Johnson M.D.

C. Device Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: *AXIS NANO* Ophthalmic Biometer Ultrasound System

Device Common Name: Ophthalmic Ultrasound System

Classification Name: System, Imaging, Ultrasonic, Ophthalmic (per 21 CFR 892.1560)

Product Code: IYO

Panel: Ophthalmology

Device Classification: Class II

D. Predicate Devices [21 CFR 807.92(a)(3)]

The *AXIS NANO* uses similar technology and physical output characteristics as the following predicate devices:

K094038 Quantel Medical *Compact TOUCH* Ophthalmic Ultrasound System

E. Device Description [21 CFR 807.92(a)(4)]

The *AXIS NANO* is an ultrasonic system designed for ophthalmic use. It uses A type scans for biometric measurements of the eye. The system is composed of a laptop computer connected an acquisition module. The A-scan probe (either TP-01-b or TP-02-las) connects to the acquisition module.

F. Device Specifications [21 CFR 807.92(a)(6)]

The *AXIS NANO* system includes an A-scan ultrasonic probe. The A-scan probe (TP-01 / TP-02-las) operates at 11 MHz and has an effective diameter of 5 mm. This probe is identical to that used by the predicate, *Compact TOUCH* cleared under k094038.

G. **Indications for Use** [21 CFR 807.92(a)(5)]

The QUANTEL MEDICAL *AXIS NANO* Ophthalmic Ultrasound System and the probes that are used with it are indicated for the biometric measurement of the eye including:

- Axial Length measurement of the eye by ultrasonic means.
- Implanted IOL power calculation, using the Axial Length measurement.

H. **Performance Data** [21 CFR 807.92(b)(2)]

Laboratory testing following the guidance "Information for manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound systems and Transducers" (Sept 9, 2008) was conducted to verify that the *AXIS NANO* met design specifications and was substantially equivalent to the predicate devices. No Clinical testing is required.

I. **Conclusion** [21 CFR 807.92(b)(3)]

Technologically, the *AXIS NANO* was found to be substantially equivalent to the currently cleared k094038 Quantel Medical *Compact TOUCH* Ophthalmic Ultrasound System. The *AXIS NANO* has only a subset of functionality that the *Compact TOUCH* has, specifically it only connects to the A-scan transducer and only does biometric measurements. It lacks the B-scan and Pachymetry functions of the *Compact TOUCH*. The indications for use are similar to the previously cleared device. The risks and benefits for the *AXIS NANO* are argued to be comparable to the predicate devices. We believe that there are no new questions of safety or efficacy raised by the introduction of the *AXIS NANO*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Quantel Medical S.A.
% Michael Johnson, M.D.
Medical Product Manager
Quantel USA
601 Haggerty Lane
BOZEMAN MT 59715

DEC 2 2 2010

Re: K102027
Trade/Device Name: AXIS NANO with Quantel Medical Transducer for Biometery
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: November 2, 2010
Received: November 5, 2010

Dear Dr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the AXIS NANO with Quantel Medical Transducer for Biometery, as described in your premarket notification:

Transducer Model Number

TP-01-b / TP-02-las

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Section 4

Indications for Use

510(k) Number (if known): NA

DEC 2 2 2010

Device Name: *AXIS NANO* Ophthalmic Biometer Ultrasound System

Indications for Use:

The QUANTEL MEDICAL *AXIS NANO* Ophthalmic Ultrasound System and the probes that are used with it are indicated for the biometric measurement of the eye including:

- Axial Length measurement of the eye by ultrasonic means.
- Implanted IOL power calculation, using the Axial Length measurement.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 810.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102027

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): NA

Device Name: *AXIS NANO* with Quantel Medical Transducer for Biometry (Ref: TP-01-b / TP-02-las).

Intended Use:

The QUANTEL MEDICAL *AXIS NANO* Ophthalmic Ultrasound System and the probes that are used with it are indicated for the biometric measurement of the eye including:

- Axial Length measurement of the eye by ultrasonic means.
- Implanted IOL power calculation, using the Axial Length measurement.

Mode of Operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	COLOR DOPPLER	POWER (AMPLITUDE) DOPPLER	COLOR VELOCITY IMAGING	COMBINED (SPECIFY)	OTHER (SPECIFY)
Ophthalmic	P									
Fetal										
Abdominal										
Intra-operative (specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Intra-luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)*										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The probes TP-01-b / TP-02-las were previously cleared in K094038.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ (Per 21 CFR 810.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102027